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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Fish & Neave
1251 Avenue of the Americas
New York, NY 10020

EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/706,128

Applicant(s)

XIE ET AL.

Examiner

Michael Borin

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16,17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16,17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/21/2005</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/21/2006 has been entered.

Status of Claims

Claims pending are 16,17,19-22.

Claim Rejections - 35 USC § 112, second paragraph.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16,17,19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons.

A. Claims 16,17,19-22 address design of inhibitor of an JNK3; however, it is not clear which JNK3 protein is meant. It is known that there is a plurality of JNK3 proteins

(see, e.g., Davis et al (US 6,943,000); teaches that there is a plurality of JNK3 proteins known (see, e.g., col. 2, lines 18,19; col. 3, last paragraph). The instant claims 16,17,20 address particular amino acid residues but it is not clear residues of which JNK3 protein are meant. Figure 1A to which claim 16 refers does not clarify which JNK3 is depicted therein.

B. Claim 16: The claim is indefinite as it addresses "coordinates according to Figure 1A; however, said Figure does not provide any coordinates. rather, said figure represents sequence alignment of various proteins.

C. Claims 16,17, 19: Claim 16 is amended to use phrase "binding pocket comprises coordinates". It is not clear how a on "binding pocket" may comprise "coordinates"; it seems that a binding pocket may comprise amino acids (such as those addressed in the claims), which amino acids, under certain circumstances, may be described by particular 3D coordinates. The claim is construed as reading on either in vitro or in silico method. Please clarify.

D. Claim 16, 20, step "using" of "all or part of a binding pocket" (claim 16) or "all or part of coordinates" (claim 20) to design inhibitor is confusing as they do not specify any positive steps involved in the process of "using". As the claims do not specify with particularity what the method steps are, it is unclear what is intended to be done.

E. Claims 16, 20: The claims are indefinite due to the lack of clarity of the claim language "using to design inhibitor" failing to recite a final process step, which agrees back with the preamble. The preamble states that it is A method for identifying inhibitor,

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however the claim recites a final step of “using to design inhibitor”, there is no indication how the inhibitor is identified. While minor details are not required in method/process claims, at least the basic step must be recited in a positive, active fashion. Clarification of the metes and bounds of the claim is requested via clearer claim wording. Incorporating limitations of claims 19 and 21 into claims 16 and 20 respectively, is suggested.

F. Claim 16, part b) addresses use of “all or part of a binding pocket”. It is not clear what “part of a binding pocket” is meant - is it down to one residue, one atom? - and what “part of coordinates” is sufficient for the instant method.

G. Similarly, claim 20, part c) addresses use of “all or part of said coordinates”. It is not clear what “part of coordinates” is meant and what “part of coordinates” is sufficient for the instant method.

Claim Rejections - 35 USC § 112, first paragraph.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16, 17, and 19-21 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for designing a ligand for JNK3 α 1 protein, does not reasonably provide enablement for any other JNK3 protein.

The instant claims are directed to method of design of inhibitor using coordinates of particular amino acid residues located at particular positions of the protein's sequence. Specification teaches that the preferred embodiment is JNK3 α 1 (see p. 8, top). All working examples are directed to use of the same JNK3 α 1. Specification does not guide how to use the invention as claimed with other JNK3 proteins having differing amino acid content and sequence.

It is known that there is a plurality of JNK3 proteins. For example, Davis et al (US 6,943,000) teaches that there is a plurality of JNK3 proteins known (see, e.g., col. 2, lines 18,19; col. 3, last paragraph). Further, as an example, Su et al (US 6,162,613) addresses JNK3 protein having Gly residue at position 150 (see claim 9) – compare to instant claims 16, 20 requiring Asp residue at the same position 150. Thus, clearly, using coordinates of JNK3 α 1 addressed in the instant specification one skilled in the art will not be able to design inhibitors to any other proteins having different amino acid sequence.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 103.

Claims 16,17,19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al. (US 6,162,613).

Su et al. discloses a method for identifying an inhibitor of JNK3 (e.g., claim 6). The method of Su et al. is based upon identification of residues in the ATP-binding pocket of kinase by crystallizing the kinase (see Summary).; by using X-ray coordinates, contact between JNK3 and inhibitors are determined via modeling and binding assays, and inhibitors are identified (Examples 4 and 5) or created (column 4, lines 16-20). The choice of inhibitor to bind to the kinase in order to generate information on close contacts depends upon the nature of the kinase. The inhibitor should bind tightly to the kinase and significantly inhibit the ability of the kinase to hydrolyze ATP. JNK3 comprising at least amino acids 40-402 of SEQ ID NO:3 is a preferred embodiment.

Even though the method disclosed by Su et al. does not specify that the atomic coordinates of JNK3 according to Figure 1, the specific limitations of atomic coordinates in this instant case do not distinguish the invention from the prior art in term of patentability because they are descriptive nonfunctional subject matter.

The following excerpt is from M.P.E.P. 2106 Section VI :

If the difference between the prior art and the claimed invention is limited to descriptive material stored on or employed by a machine, Office personnel must determine whether the descriptive material is functional descriptive material or nonfunctional descriptive material, as described supra in paragraphs IV.B.1(a) and IV. B.1(b).

Nonfunctional descriptive material cannot render nonobvious an invention that would have otherwise been obvious. In re Ngai, F.3d, 2004 WL 1068957 (Fed. Cir. May 13, 2004).< Cf. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 404 (Fed. Cir. 1983)

Common situation involving nonfunctional descriptive material is a process that differs from the prior art only with respect to nonfunctional descriptive material that cannot alter how the process steps are to be performed to achieve the utility of the invention.

Specific to the instant case, atomic coordinates in Figure 1 are merely stored so as to be read or outputted by a computer without creating any functional interrelationship, either as part of the stored data or as part of the computing processes

performed by the computer, then such descriptive material alone does not impart functionality either to the data as so structured, or to the computer.

Response to arguments

Applicant argues that the data of Table 1 is functional descriptive material because the computer converts them into novel 3D representation of JNK3 protein. Examiner disagrees. The data of Figure 1A do not alter how the process steps of Su et al. are to be performed. Further, with respect to applicant's emphasis on JNK3 protein being non-phosphorylated, teaching of Su et al is not specifically directed to use of phosphorylated JNK3; contrary, Example 5, describing crystallization and structure determination teaches use of unphosphorylated protein, ERK2 (JNK3 is addressed in the same example as to be used similarly to ERK2). If applicant views Example 4 in Su et al as evidence for the use of phosphorylated protein, said example is not directed to crystallization and structure determination.

Claims 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al. (US 6,943,000; effective filing date 10/03/1997) in view of Gupta et al. (The EMBO Journal vol.15 no.11, pp.2760-2770. 1996; reference presented by applicant)

The claims are directed to method for identifying JNK3 inhibitor by producing a crystal of unphosphorylated JNK3, containing N-terminal deletion of 39 amino acids, determining the three dimensional atomic coordinates of particular amino acids (see part (b) of claim 20) by X-ray diffraction of the crystal, and using all or part of said coordinates to design or select an inhibitor.

Davis et al is directed to identification and use of JNK3 modulators. The reference teaches that computer modeling is used to identify compounds that modulate activity of a JNK3 protein by reacting, for example with its active site. The active site of JNK3 can be identified using methods known in the art including, for example, X-ray crystallographic methods. Having determined the structure of the active site of a JNK3 protein, candidate modulating compounds can be identified; the compounds identified in such search are those that have structures that match the active site structure, fit into the active site, or interact with groups defining the active site. The compounds identified by the search are potential JNK3 modulating compounds. See col. 7. The method of Davis et al is applicable to any of known JNK3 proteins (see col. 3, bottom); the reference teaches that there is a plurality of JNK3 proteins known (see, e.g., col. 2, lines 18,19).

The reference does not teach use of JNK3 protein having particular residues as now addressed in claim 20, part (b). However, as the reference is not directed to any particular JNK3 isoform (see preceding paragraph), it would be *prima facie* obvious to an artisan that any JNK3 protein of interest can be used in the method of Davis et al. For example, it would be obvious to use JNK3 α human isoform described in Gupta et al., which is the preferred embodiment of the instant invention.

Further, Davis et al does not address use of a truncated JNK3 protein as claimed in instant 20,22. However, the reference does not teach that identifying inhibitor requires full-length protein; contrary, the reference states that a digital model of active site is required (see, e.g., col. 6, lines 60-62 , col. 7. Therefore, it would be obvious to

an artisan that non-essential residues non-participating in the active site or binding pocket may be omitted from design of 3D model and search of the inhibitor.

Conclusion.

No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (571) 272-0713. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL BORIN, PH.D.
PRIMARY EXAMINER



Michael Borin, Ph.D.